REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action.

The provisional rejection of claims 1-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending application 09/926,602 (actually 09/926,002) has been obviated by the filing herewith of a Terminal Disclaimer and payment of the required fee. Accordingly, it is most respectfully requested that the provisional rejection be withdrawn.

The rejections of claims 1, 3, 4 and 5 under 35 U.S.C. 112 have been carefully considered but are most respectfully traversed in view of the amendments to the claims. In this regard, claims 1-10 have been canceled from the application and replaced with claims 11-46. Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

Claim 1, corresponds to claim 11 now present in the application. This claim does not include the objected to term "unsaturated" from the description of the acyl group in the monoglyceride and fatty acid and it is most respectfully requested that this aspect of the rejection be withdrawn. The amendment to the claims are fully supported by Applicants' specification.

It is to be noted that in rewriting the claims, the number of carbon atoms in the fatty acid has been increased by two from the range of values in the original claims. This is because the structural formula is not present in the claims. As is evident to one of ordinary skill in the art from Applicants' specification, the designation of "n" as varying between 4 and 22 has been increased by the two carbon atoms shown in the formula on page 5 but not included in the range 4 and 22. Clearly, these two additional carbon atoms and the structural formula for the fatty acids clearly support the limitation for the fatty acid as containing from 6 to 24 carbon atoms as set forth in the new claim set.

In addition, the alternative language has been removed from the claims and proper Markush language has been used where appropriate. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-9 under U.S.C. 103 as being unpatentable over Youmans et al. in view of Schroder has been carefully considered but is most respectfully traversed.

These claims have been rejected on the basis that the Examiner finds that it would have been prima facie obvious to add the monoglyceride preparation as taught by Schroder to the *Mycobacterium tuberculosis* vaccine of Youmans et al.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

The problem to be addressed by the presently claimed invention is the formulation of an improved TB vaccine.

Even though the prior art of Schroder suggests an adjuvant for use in a vaccine formulation, it does not suggest a TB vaccine. The only examples mentioned in patent application by Schroder are vaccines comprising diphtheria toxoid, influenza virus, and rotavirus.

According to the Examiner, Youmans et al. teaches a tuberculosis vaccine comprising heat or chemically killed *Mycobacterium tuberculosis*.

The paper by Youmans et al. contains a comparison between tuberculosis vaccine comprising either viable attenuated cells or heat or chemically killed cell. The results shown clearly states that living cells prove to be several hundred times more effective as immunizing agents against tuberculous infection than autoclaved cells or cells inactivate by chemical agents. Actually, in the conclusion (p. 112, column 2, last sentence) is stated that living and killed mycobacterial cells differ not only quantitatively in their capacity to immunize against tuberculous infection, but qualitatively as well, the living cells being far more effective as immunizing agents.

Thus, there is no indication that a TB vaccine comprising inactivated *Mycobacterium tuberculosis* would be especially effective.

Furthermore, page 111, 2 column in Youmans et al. reads:

"There is little indication from the data that immunizing activity of whole cells, whether viable or killed, was affected appreciably by being administered in Fruend's incomplete adjuvant".

Since the paper clearly describes very little, if any, success in administering the *M. tuberculosis* cells together with adjuvant, it certainly does not render it obvious to produce a TB vaccine composition as described and claimed in the present application comprising whole cell *M. tuberculosis* together with an adjuvant.

Applicants believe the teaching of the known prior art by Schroder and Youmans neither taken alone nor in combination provide any hint to use the adjuvants of Schroder in the formulation of a TB vaccine comprising **inactivated** *M. tuberculosis* cells or the success of this vaccine. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Youmans et al. in view of Schroder has been carefully considered but is most respectfully traversed.

Claim 10 is rejected as being unpatentable over Youmans et al. in view of Schroder. Applicants most respectfully that for the reasons discussed above, a prima facie case of obviousness has not been established.

The method used for vaccinating a mammal against tuberculosis as now claimed includes the administration of a vaccine composition comprising the L3 adjuvant and inactivated mycobacterium. As describes above, Youmans et al. does not teach the use of adjuvants as beneficial, and furthermore, the method using inactivated *M. tuberculosis* cells provides very poor results.

Thus, Applicants find, that based on the prior art it would not be rendered obvious, that a combination of the monoglyceride preparation of Schroder and an inactivated strain of mycobacterium would provide an effective method for vaccinating a mammal. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims and the submission herewith of a Terminal Disclaimer, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,

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